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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/675,920	09/30/2003	Christopher P. Knapp	279.640US1	2079

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FAEGRE & BENSON LLP
PATENT DOCKETING - INTELLECTUAL PROPERTY (32469)
2200 WELLS FARGO CENTER
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MINNEAPOLIS, MN 55402-3901

EXAMINER	
KAHELIN, MICHAEL WILLIAM	
ART UNIT	**PAPER NUMBER**
3762	

NOTIFICATION DATE	DELIVERY MODE
08/16/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/675,920	KNAPP ET AL.	
	Examiner	Art Unit	
	MICHAEL KAHELIN	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2010*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6-9,15-20,22-25,30-40 and 44-52* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6-9,15-20,22-25,30-40 and 44-52* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *20100510*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 7/14/2010 has been entered.

Claim Objections

2. Claim 6 is objected to because of the following informalities: "wherein second" should read "wherein the second". Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-4, 6-9, 15-20, 22-25, 30-40, and 44-52 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In regards to claims 1, 16, 30, and 35, it is unclear whether the limitation drawn to a layer consisting of a second pharmacological agent excludes only a time-release element (*e.g.*, polymer matrix), or excludes any and all elements besides the drug. In other words, the disclosure indicates that, unlike the layer(s) below which include drug and a polymer matrix, this layer is "pure drug." Is this a "pure drug" in the sense that it

does not include the matrix of the other layers, or is this a “pure drug” in the sense that it is pure active ingredient that is free of the inactive ingredients commonly used in drugs/pharmacological agents (*e.g.*, binders, fillers, lubricants, preservatives, carriers, etc.)? For the purposes of interpreting these claims, the examiner is considering such excipients to be "impurities ordinarily associated" with active ingredients, and thus the claim scope precludes a time-release structure such as the polymer matrix, but allows for excipients. *See* MPEP § 2111.03. However, the record should be clarified.

6. In regards to claims 6, 22, and 36, the claim from which these claims depend recite a layer that "consists of a pharmacological agent” (singular), but these claims recite that this layer can include a combination of drugs. When a “consisting of” limitation is used, dependent claims cannot add elements or steps. *See* MPEP § 2111.03.

7. In regards to claims 35, 36, and 44, two layers are claimed as including “at least one pharmacological agent,” rendering it unclear whether both layers are reciting the same pharmacological agent or different agents. Regarding the dependent claims, it is unclear as to which of the two agents or coatings the claims refer.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

10. Claims 1-4, 6-9, 15-20, 22-25, 30-40, 44, and 45 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolz et al. (US 5,964,794, hereinafter “Bolz”) in view of Stokes (US 4,506,680, hereinafter "Stokes").

11. In regards to claims 1, 16, 30, 32, 33, and 35, Bolz discloses providing a pulse generator (Fig. 6); a lead having a body and conductor (Fig. 5); and an electrode (Fig. 8, element 1a) having a coating with a first layer adjacent the surface of the electrode (1b”’ closest to 1a) including an insulative material (col. 9, lines 21-27), a second layer disposed over the first layer and not adjacent to the surface of the electrode (second 1b"' layer from electrode 1a), the layer including at least one pharmacological agent (1c”’), and a third layer disposed over the second layer (third 1b”’ layer from electrode 1a), wherein the third layer includes at least one pharmacological agent (1c”’). Bolz does not expressly disclose that the third layer consists of a pharmacological agent. However, Stokes teaches that it is known to coat drug-eluting leads with an outer layer of consisting of a pharmacological agent (col. 3, lines 48-57) to provide the predictable

results of facilitating drug flow from the device into the tissue and provide a more robust acute delivery. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Bolz's invention by providing an outer layer of consisting of a pharmacological agent to provide the predictable results of facilitating drug flow from the device into the tissue and provide a more robust acute delivery.

12. In regards to claims 3, 18, and 36, the pharmacological agent is an anti-inflammatory (col. 9, lines 20-28).

13. In regards to claims 6 and 22, the first layer is a polymeric base coat (claim 2), and the second layer is a matrix of polymer and pharmacological agent (col. 9, lines 20-28).

14. In regards to claims 9, 25, 39, 40, and 44 the electrode further comprises a porous polymeric fourth layer (Fig. 8; "porous" because the drug molecules from the lower layers can escape and this layer regulates their escape) and is polymeric (claim 2, col. 6, line 22).

15. In regards to claim 15, the first layer increases impedance (col. 9, line 24).

16. In regards to claims 2, 4, 7, 8, 14, 17, 19, 20, 23, 24, 31, 34, 37, 38, and 45, Bolz discloses the essential features of the claimed invention except for a helical tip electrode, an anti-inflammatory of the claimed types, a base coat of ethylene vinyl alcohol, a pharmaceutical agent including an anti-proliferative drug, or applying the coatings by spraying. However, Applicant admitted prior art teaches that it is well

known in the implantable device arts to provide helical tip electrodes to provide the predictable results of solid lead fixation, an anti-inflammatory of the claimed types to provide the predictable results of avoiding inflammation with known substances, ethylene vinyl alcohol in implantable devices to provide the predictable results of an implantable polymer with known biocompatability, a pharmaceutical agent including an anti-proliferative drug to provide the predictable results of avoiding the formation of scar tissue around the electrode, and applying the coatings by spraying to provide the predictable results of ease of manufacturability of the electrode. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Bolz's invention by providing helical tip electrodes to provide the predictable results of solid lead fixation, an anti-inflammatory of the claimed types to provide the predictable results of avoiding inflammation with known substances, ethylene vinyl alcohol in implantable devices to provide the predictable results of an implantable polymer with known biocompatability, a pharmaceutical agent including an anti-proliferative drug to provide the predictable results of avoiding the formation of scar tissue around the electrode, and applying the coatings by spraying to provide the predictable results of ease of manufacturability of the electrode. Based on Applicant's failure to traverse the taking of Official Notice with regards to claims 2, 4, 7, 8, 14, 17, 19, 20, 23, 24, 31, 34, 37, 38, and 45 in the Office Action of 4/21/2010, the Examiner is considering these features to be Applicant admitted prior art. See MPEP § 2144.03(c).

17. Claims 46, 48, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolz and Stokes, as applied to claims 1, 16, and 51 above, and further in view of Weidlich et al. (US 5,103,837, hereinafter "Weidlich"). Bolt discloses the essential features of the claimed invention except for a first layer that is between 1 and 100 microns thick. However, Weidlich teaches a polymeric first layer that is between 1 and 100 microns thick (claims 16 and 17) to provide the predictable results of maintaining desired polarization properties, while still having a thin lead suitable for intracardiac placement. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Bolz by providing a polymeric first layer that is between 1 and 100 microns thick to provide the predictable results of maintaining desired polarization properties, while still having a thin lead suitable for intracardiac placement.

18. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Bolz and Stokes, as applied to claim 30 above, and further in view of Osypka et al. (US 7,187,980, herinafter "Osypka"). Bolz discloses the essential features of the claimed invention except for explicitly indicating a layer having up to 60% by weight of pharmacological agent. However, Osypka teaches an implantable drug-eluting electrode having a elution layer of up to 60% by weight of pharmacological agent (abstract -- "up to" including the range of 0-60%) to provide the predictable results of effectively controlling the long-term rate of drug release to the patient. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention

was made to modify Bolz by providing an implantable drug-eluting electrode having a elution layer of up to 60% by weight of pharmacological agent to provide the predictable results of effectively controlling the long-term rate of drug release to the patient.

19. Claims 47, 49, and 52 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bolz, Stokes, and Weidlich, as applied to claims 46, 48, and 51 above, and further in view of Osypka et al. (US 7,187,980, herinafter "Osypka"). Bolz discloses the essential features of the claimed invention except for explicitly indicating a layer having up to 60% by weight of pharmacological agent. However, Osypka teaches an implantable drug-eluting electrode having a elution layer of up to 60% by weight of pharmacological agent (abstract -- “up to” including the range of 0-60%) to provide the predictable results of effectively controlling the long-term rate of drug release to the patient. Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Bolz by providing an implantable drug-eluting electrode having a elution layer of up to 60% by weight of pharmacological agent to provide the predictable results of effectively controlling the long-term rate of drug release to the patient.

Response to Arguments

20. Applicant's arguments with respect to claims 1-4, 6-9, 15-20, 22-25, 30-40, and 44-52 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MICHAEL KAHELIN whose telephone number is (571)272-8688. The examiner can normally be reached on M-F, 9-5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel can be reached on (571) 272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael Kahelin/
Examiner, Art Unit 3762